REMARKS

Claims 1, 2, and 4 – 20 are currently pending. Claim 1 is the only independent claim. The Examiner has rejected Claims 1 – 20 as allegedly anticipated by PCT Application WO 01/87329 to Papadimitriou. In addition, Claim 2 was rejected under Section 112, second paragraph as allegedly indefinite. Finally, the Examiner issued a provisional "obviousness-type" double patenting rejection against Claims 1 – 10 based upon Claims 1 – 9 of copending U.S. Application Serial No. 10/521,296.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Prior Art Rejections.

In response to the art rejections based on the Papadimitriou reference, Applicants note that independent Claim 1, as amended herein, now calls for a stable pharmaceutical composition of erythropoietin (EPO), wherein the composition consists essentially of (a) a therapeutically effective amount of EPO, (b) a pharmaceutically acceptable pH buffering system, (c) a poloxamer polyol, (d) a polyhydric alcohol and, optionally, (e) an isotonifying agent. Thus, the composition called for in Claim 1 is now partially closed with respect to additional components which would "materially affect the basic and novel characteristics" of the claimed invention. *See Atlas Powder Co. v. E.I. du Pont de Memours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *PPG Industries v. Guardian Industries Corp.* 156 F.3d 1351, 48 USPQ2d 1351 (Fed. Cir. 1998).

Claim 1 as amended is novel and patentably distinguishable over Papadimitriou because Papadimitriou teaches the need to include an antioxidant such as methionine in any "stable" EPO composition. The specific compositions disclosed on pages 22 and 23 of Papadimitriou include methionine as an antioxidant. Example 11 of the Papadimitriou reference likewise emphasizes the need to include antioxidants such as methionine in the composition.

Papadimitriou requires methionine in its EPO compositions and the presence of an antioxidant such as methionine would "materially affect the basic and novel characteristics" of the composition. It follows then that the Papadimitriou reference cannot lawfully be said to anticipate the subject matter of Claim 1. Further, since the Papadimitriou reference fails to

anticipate Claim 1, it also fails to anticipate any of claims 2 & 4 – 20. which depend from Claim 1.

II. The Indefiniteness Rejection.

The Examiner also contends that Claim 2 is indefinite for purposes of 35 U.S.C. §112. Specifically, the Examiner argues that the nature of the "additives" in the limitation "wherein the composition is free of additives derived from human and/or animal origin" is unclear. Applicants respectfully disagree.

The meaning of this limitation is and will be reasonably and sufficiently clear to one of ordinary skill in the art. particularly in view of Applicant's specification. At page 5, the specification instructs that the term "free of additives derived from human and/or animal origin" refers to:

> the condition that additives which originate from human and/or animal and which are different from EPO. such as serum albumins like HSA or BSA. are not intentionally added to the composition. or if originally present in an EPO preparation have been separated or reduced during the purification and/or isolation of EPO to an unavoidable level of traces. preferably to a level that is typically undetectable by standard analytical methods.

Accordingly, it is plain that the meaning of the limitation in question is and would be reasonably discernable to a person of ordinary skill from Applicants' specification. It simply means that a composition according to claim 2 is substantially free of any materials which originate from human and/or animal origin other than EPO. To further clarify this point, Applicants have herein amended Claim 2 to specify that the composition is substantially free of additives derived from human and/or animal origin, other than EPO. It is therefore respectfully urged that this amendment and the accompanying explanation overcomes and/or satisfactorily addresses any possible or asserted ambiguity in the language of the claim, and that the indefiniteness rejection of Claim 2 should accordingly be withdrawn.

III. The Provisional Double Patenting Rejections.

Finally, the Examiner has issued a provisional "obviousness-type" double patenting rejection against Claims 1 – 10 based upon Claims 1 – 9 of copending U. S. Application Serial

No. 10/521,296. Such rejections are of course obviated by the filing of an appropriate terminal disclaimer. A terminal disclaimer is submitted herewith for this purpose disclaiming that portion of the patent term of the patent to issue from this application which would extend beyond the term of any commonly owned patent which may issue from the '296 application. Accordingly, the double patenting rejection is overcome and the same should be withdrawn.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw all rejections, and to issue a Notice of Allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted.

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